IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

THOMAS SCHROEDER,

Plaintiff,

and

MEDTRONIC, INC.,

Plaintiff/Intervenor,

vs.

THE UNITED STATES DEPARTMENT OF VETERANS AFFAIRS,

Defendant.

Case No. 22-2209-DDC-KGG

MEMORANDUM AND ORDER

Plaintiff Thomas Schroeder filed this lawsuit against the United States Department of Veterans Affairs ("VA") under the Administrative Procedures Act ("APA"), 5 U.S.C. § 706. Doc. 9. He asks the court to issue an order compelling the VA to produce certain documents and information within the VA's sole possession. About five months after plaintiff Thomas Schroeder filed this action, plaintiff-intervenor Medtronic, Inc. filed an Intervenor Complaint (Doc. 19). It also asserts an APA claim and seeks a court order compelling the VA to produce certain documents and information within the VA's sole possession.

For reasons explained below, the court concludes that the VA's refusal to provide the documents and information requested by plaintiff Schroeder was arbitrary, capricious, and an abuse of discretion under the APA. Also, the court concludes, the VA's refusal to provide the documents and information sought by plaintiff-intervenor Medtronic, Inc. was arbitrary,

capricious, and an abuse of discretion under the APA. As a consequence, the court remands the matter to the VA for further consideration of plaintiff Schroeder and plaintiff-intervenor Medtronic, Inc.'s requests for documents and information. The court explains how it reaches these conclusions, below.

I. Factual and Procedural Background

The court recites the following factual and procedural background relevant to the APA claims against the VA.

The Qui Tam Action

In a separate lawsuit, plaintiff Thomas Schroeder, as "relator," has brought a qui tam action on behalf of the United States government in the United States District Court for the District of Kansas. Doc. 9 at 2 (First Am. Compl. ¶ 6). The qui tam action is styled *United States ex rel. Schroeder v. Medtronic, Inc.*, No. 17-2060-DCC-KGG (D. Kan.). *Id.*; *see also* Fifth Amended Complaint, *U.S. ex rel. Schroeder v. Medtronic, Inc.*, No. 17-2060-DDC-KGG (D. Kan. Oct. 24, 2022), ECF No. 233. That action asserts violations of the False Claim Act, 31 U.S.C. §§ 3729–3733, against various defendants, including Medtronic, Inc. ("Medtronic"). Doc. 9 at 2 (First Am. Compl. ¶ 7); *see also* Fifth Amended Complaint, *U.S. ex rel. Schroeder v. Medtronic, Inc.*, No. 17-2060-DDC-KGG (D. Kan. Oct. 24, 2022), ECF No. 233. The VA is not a party to the qui tam lawsuit. *Id.*

The qui tam action asserts that Medtronic paid illegal remuneration to employees at the Dole VA. Doc. 9 at 3 (First Am. Compl. ¶ 8). Relator alleges that the illegal remuneration caused the VA to purchase a grossly excessive number of medical devices, provide unnecessary medical treatment, and promote off-label use of devices on Dole VA's veteran patients. *Id.*

Relator asserts that these actions violated the False Claims Act/Anti-Kickback Statute. *Id.* (citations omitted).

During fact discovery in the qui tam case, relator has sought nonprivileged and relevant fact discovery from parties and non-parties, including the VA. *Id.* (First Am. Compl. ¶ 9).

The VA's* Touhy *Regulations

Section 301 of Title 5 of the United States Code provides that a federal agency "may prescribe regulations for . . . the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301. These regulations are known as *Touhy* regulations. *See U.S. ex rel. Touhy v. Ragen*, 340 U.S. 462, 467–68 (1951) (holding that DOJ official properly could refuse to comply with a subpoena duces tecum based on a valid regulation issued by the Attorney General under an earlier version of 5 U.S.C. § 301 restricting disclosure of DOJ records); *see also Hous. Assistance Corp. of Nassau Cnty. v. Fernandina Beach RRH, Ltd.*, No. 3:08-cv-782-J-32JRK, 2008 WL 11433239, at *2 (M.D. Fla. Oct. 9, 2008) (explaining that, after *Touhy*, federal regulations enacted under 5 U.S.C. § 301 "became known as *Touhy* regulations").

The VA has codified its *Touhy* policies and procedures for "production or disclosure of official information or records of the Department of Veterans Affairs (VA)" in the Code of Federal Regulations. 38 C.F.R. § 14.800 (citing 38 C.F.R. §§ 14.800–14.810). The VA's *Touhy* regulations provide that VA personnel may not provide testimony or produce VA records in legal proceedings "without the prior written approval of the responsible VA official designated in § 14.807(b)." 38 C.F.R. § 14.806. Section 14.807(b) designates the responsible VA official as "the General Counsel, the Regional Counsel, an attorney in the Office of General Counsel designated by the General Counsel, or an attorney in the Regional Counsel office designated by the Regional Counsel." 38 C.F.R. § 14.807(b).

A party who seeks documents or testimony from the VA must make a proper request under the VA's *Touhy* regulations by submitting:

> a written statement by the party seeking the testimony or records or by the party's attorney, [along with] a summary of the nature and relevance of the testimony or records sought in the legal proceedings containing sufficient information for the responsible VA official to determine whether VA personnel should be allowed to testify or records should be produced.

38 C.F.R. § 14.805. The VA *Touhy* regulations provide 15 factors for the responsible VA official to consider when deciding whether to produce the requested information. 38 C.F.R. § 14.804. They include:

> (a) The need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel for conducting their official duties concerning servicing the Nation's veteran population;
>
> (b) How the testimony or production of records would assist VA in performing its statutory duties;
>
> (c) Whether the disclosure of the records or presentation of testimony is necessary to prevent the perpetration of fraud or other injustice in the matter in question;
>
> (d) Whether the demand or request is unduly burdensome or otherwise inappropriate under the applicable court or administrative rules;
>
> (e) Whether the testimony or production of records, including release in camera, is appropriate or necessary under the rules of procedure governing the case or matter in which the demand or request arose, or under the relevant substantive law concerning privilege;
>
> (f) Whether the testimony or production of records would violate a statute, executive order, regulation or directive. (Where the production of a record or testimony as to the content of a record or about information contained in a record would violate a confidentiality statute's prohibition against disclosure, disclosure will not be made. Examples of such statutes are the Privacy Act, 5 U.S.C. 552a, and sections 5701, 5705 and 7332 of title 38, United States Code.);
>
> (g) Whether the testimony or production of records, except when in camera and necessary to assert a claim of privilege, would reveal information properly classified pursuant to applicable statutes or Executive Orders;

(h) Whether the testimony would interfere with ongoing law enforcement proceedings, compromise constitutional rights, compromise national security interests, hamper VA or private health care research activities, reveal sensitive patient or beneficiary information, interfere with patient care, disclose trade secrets or similarly confidential commercial or financial information or otherwise be inappropriate under the circumstances[;]

(i) Whether such release or testimony reasonably could be expected to result in the appearance of VA or the Federal government favoring one litigant over another;

(j) Whether such release or testimony reasonably could be expected to result in the appearance of VA or the Federal government endorsing or supporting a position advocated by a party to the proceeding;

(k) The need to prevent the public's possible misconstruction of variances between personal opinions of VA personnel and VA or Federal policy[;]

(l) The need to minimize VA's possible involvement in issues unrelated to its mission;

(m) Whether the demand or request is within the authority of the party making it;

(n) Whether the demand or request is sufficiently specific to be answered;

(o) Other matters or concerns presented for consideration in making the decision.

Id.

The VA *Touhy* regulations provide that "the VA official"—after considering the request—"shall determine in writing whether the individual is required to comply with the demand or request and shall notify the requester or the court or other authority of the determination reached where the determination is that VA will not comply fully with the request or demand." 38 C.F.R. § 14.807(c).

Plaintiff Schroeder's* Touhy *Requests to and Responses from the VA

Beginning in January 2022, consistent with the VA's *Touhy* regulations, plaintiff Schroeder sent written requests for testimony and documents to the VA. Doc. 14-2 at 132–47, 148–53, 170–72 (AR 499–514, 515–19, 537–39); Doc. 14-3 at 28–30, 112–13 (AR 575–77, 659–60); Doc. 14-4 at 1–4 (AR 661–64). Specifically, plaintiff Schroeder sought from the VA

various documents, data, and depositions of current and former VA personnel relevant to his underlying False Claims Act lawsuit. *Id.*

On June 15, 2022, the VA sent plaintiff Schroeder a written response to his *Touhy* requests. Doc. 14-2 at 124–30 (AR 491–97). It addressed some of plaintiff Schroeder's document requests but not the deposition testimony sought. *Id.* The VA concluded the letter by stating that it "will not authorize the production of documents you seek[.]" *Id.* at 125 (AR 492). As support for its decision to withhold production of the requested information, the VA relied on several factors found in 38 C.F.R. § 14.804. Specifically, the VA cited the following § 14.804 factors: subsection (a)'s "need to avoid spending the time and money of the United States for private purposes" factor; subsection (d)'s "unduly burdensome" factor; subsection (f)'s "confidentiality" factor; and subsection (*l*)'s "need to minimize VA's involvement in issues unrelated to its mission" factor. *Id.* at 124–25 (AR 491–92). The VA's letter also provided a time and cost estimate for producing the requested documents and information. *Id.* at 125 (AR 492). It estimated that the production would require 9,850 hours of VA staff time and cost $474,417.15. *Id.*

After receiving the VA's initial response, plaintiff Schroeder's counsel and the VA engaged in several good faith communications about the discovery requests. Doc. 9 at 5 (First Am. Compl. ¶ 22). As a result of these communications, plaintiff Schroeder resubmitted his requests for documents and information, significantly reducing the size and scope of the requested documents, information, and testimony. *See* Doc. 14-2 at 153–57 (AR 520–24). After resubmitting the request, plaintiff Schroeder's counsel and the VA were able to reach an agreement on many of the requested documents and much of the requested testimony. Doc. 9 at 6 (First Am. Compl. ¶ 23). Specifically, the VA agreed to depositions of three former employees

and one current employee of the Dole VA, subject to reasonable conditions. *Id.* (First Am. Compl. ¶ 24). And, in response to some of the document requests, the VA already has produced documents and has agreed to produce other documents and information in its possession. *Id.* The VA conditioned these agreements on plaintiff Schroeder's reciprocal agreement to pay the VA for its costs to produce the additional documents and information. *Id.* Plaintiff Schroeder asserts that some of these documents support his allegations of medically unnecessary treatment, including documents from the VA's investigation reporting:

- "Evidence based medicine not followed in majority of the cases. Total disregard for TASC II recommendations for [peripheral artery disease devices.]" Doc. 14-1 at 335 (AR 331).
- "The cocktail of devices used in quite a few cases. Is it really [warranted] even though the end results are not that different and add to complications." *Id.*
- "Seems like over utilization of [drug coated balloons] and atherectomy devices[.]" *Id.*

Notwithstanding the VA's agreement to produce some documents and information, the VA has told plaintiff Schroeder that it will not produce other documents and information sought by his *Touhy* requests. *See generally* Doc. 14-2 at 163–65 (AR 530–32). Specifically, the VA has declined to produce the following four categories of documents and information:

1. "Data reflecting the annual number of interventional procedures performed at the Dole VA cath lab by interventional radiologists for the years 2011 through 2018." Doc. 14-2 at 167 (AR 534). In a September 20, 2022 letter, the VA told plaintiff Schroeder that it would not produce the requested data and that it objected to the

request because the documents are medical records "that are protected by the Privacy Act, HIPAA, FOIA, and/or related privacy statutes." *Id.*

2. "A statistically acceptable sample of patients' medical records regarding interventional procedures performed in the Dole VA cath lab by interventional radiologists for the years 2011 through 2018." *Id.* at 167 (AR 534). The VA's September 20, 2022 letter told plaintiff Schroeder that the VA wouldn't produce these documents for the same confidentiality reasons it had declined to produce the data described in the above paragraph. *Id.* Also, the VA stated that it would cost an estimated $21,387.52 for the VA to produce the data and records sought by this request and the one in the above paragraph. *Id.* at 169 (AR 536).
3. "Documents that address any complaints or investigation into conduct at the Dole VA's catheterization lab involving Medtronic, Inc. or Covidien, Inc., or their representatives[.]" Doc. 14-3 at 31 (AR 578). The VA already has produced some documents responsive to this request, but plaintiff Schroeder believes that additional documents exist that fall within the scope of this request. *See* Doc. 32 at 12 (citing AR 1–360). In an August 15, 2022 letter, the VA declined to produce the records citing the following three § 14.804 factors: (1) subsection (a)'s "need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel" factor; (2) subsection (i)'s "appearance of VA or the Federal government favoring one litigant over another" factor; and (3) subsection (*l*)'s "need to minimize VA's possible involvement in issues unrelated to its mission" factor. Doc. 14-3 at 31–32 (AR 578–79).

4. "Documents that reflect any audits or studies comparing the costs or clinical outcomes of performing procedures at the Dole VA's catheterization lab compared to other facilities performing the same procedures." Doc. 14-2 at 165–66 (AR 532–33). In the September 20, 2022 letter, the VA agreed to produce some documents responsive to this request that did "not require an extensive/time consuming search of its records, and [was] not protected by privacy laws[.]" *Id.* at 166 (AR 533). But the VA refused to produce any "other documents that require an extensive/time consuming search . . . until the [VA] receives payment from [plaintiff Schroeder]" for the costs of producing the documents. *Id.* The VA estimated the costs of the production as $17,443.20. *Id.* at 169 (AR 536). Plaintiff Schroeder asserts that the VA's estimated costs for the production "are excessive for what is being requested." Doc. 9 at 7 (First Am. Compl. ¶ 25.c.).

Plaintiff Schroeder asserts that the VA's August 15, 2022 and September 20, 2022 letters (Doc. 14-2 at 161–69 (AR 528–36); Doc. 14-3 at 31–32 (AR 578–79))—ones that refuse to comply fully with plaintiff Schroeder's *Touhy* requests—serve as its "final agency action" for purposes of plaintiff Schroeder's APA claim. Doc. 9 at 7 (First Am. Compl. ¶ 26 (citing *Ctr. for Native Ecosystems v. Cables*, 509 F.3d 1310, 1329 (10th Cir. 2007) ("If an agency has issued a definitive statement of its position, determining the rights and obligations of the parties, the agency's action is final [for purposes of an APA action]" (citations and internal quotation marks omitted)))).

Plaintiff-Intervenor Medtronic's* Touhy *Requests to and Responses from the VA

As already explained, plaintiff Schroeder's underlying qui tam lawsuit names Medtronic as one of the defendants. *See* Fifth Amended Complaint, *U.S. ex rel. Schroeder v. Medtronic,*

Inc., No. 17-2060-DDC-KGG (D. Kan. Oct. 24, 2022), ECF No. 233. Medtronic disputes plaintiff Schroeder's claims that it has violated the False Claims Act and "contends that Relator's theories and allegations lack merit." Doc. 19 at 3 (Intervenor Compl. ¶ 8).

Although plaintiff Schroeder bases his claims in the qui tam lawsuit on alleged wrongdoing at the Dole VA, he sought fact discovery on peripheral vascular device use at 11 other VA facilities. *Id.* at 3 (Intervenor Compl. ¶ 9). Medtronic objected to plaintiff Schroeder's discovery requests for the 11 other VA hospitals in addition to the Dole VA, but the court overruled those objections and permitted the discovery. *Id.* Medtronic asserts that plaintiff Schroeder's discovery requests for the 11 other VA hospitals has "forced" Medtronic also to seek fact discovery from the VA—discovery that involves both the Dole VA and 11 other VA facilities. *Id.*

On August 2, 2022, consistent with the VA's *Touhy* regulations, Medtronic sent its written request for testimony and documents to the VA. *Id.* at 5 (Intervenor Compl. ¶ 17); *see also* Doc. 25-1 at 1–11 (AR 692–702). Medtronic asserts that it "properly followed the VA's regulations by providing a detailed summary of the nature and relevance of the testimony and records sought in the underlying qui tam action such that the responsible VA official could determine whether to comply and, if so, to what extent." Doc. 19 at 5 (Intervenor Compl. ¶ 17) (citing 38 C.F.R. §§ 14.804, 14.805).

On October 4, 2022, the VA provided Medtronic with a written response to Medtronic's *Touhy* requests. *Id.* (Intervenor Compl. ¶ 18); *see also* Doc. 25-1 at 12–26 (AR 703–17). In response to Medtronic's *Touhy* requests, the VA produced some documents responsive to one of Medtronic's document requests and permitted several depositions. *Id.* But the VA objected to the remaining document requests. *Id.* To support its objections to the document requests, the

VA cited some of the factors promulgated by 38 C.F.R. § 14.804. Doc. 25-1 at 13–14 (AR 704–05). Specifically, the VA cited: (1) subsection (a)'s "need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel" factor; (2) subsection (d)'s "unduly burdensome" factor; (3) subsection (f)'s "confidentiality" factor; and (4) subsection (*l*)'s "need to minimize VA's involvement in issues unrelated to its mission" factor. *Id.* The VA also provided a time and cost estimate for producing the requested documents and information of about 6,117.25 hours and $266,474.89. *Id.* at 14 (AR 705).

Medtronic asserts that the VA's October 4, 2022 letter refusing to comply fully with Medtronic's *Touhy* requests is its "final agency action" for purposes of plaintiff Schroeder's APA claim. Doc. 19 at 5–6 (Intervenor Compl. ¶ 20 (citing *Ctr. for Native Ecosystems*, 509 F.3d at 1329 ("If an agency has issued a definitive statement of its position, determining the rights and obligations of the parties, the agency's action is final [for purposes of an APA action.]" (citations and internal quotation marks omitted))).

II. Legal Standard

The APA grants federal courts authority to review agency decisions. *See* 5 U.S.C. § 702. "A party challenging an agency's *Touhy*-based denial of a subpoena or request for testimony 'must proceed under the APA, and the federal court will review the agency's decision not to permit its employee to testify under an "arbitrary and capricious" standard.'" *Bobreski v. U.S. EPA*, 284 F. Supp. 2d 67, 73–74 (D.D.C. 2003) (quoting *Houston Bus. J., Inc. v. Off. of Comptroller of Currency, U.S. Dep't of Treasury*, 86 F.3d 1208, 1212 n.4 (D.C. Cir. 1996) (further citation omitted)); *see also Edwards v. U.S. DOJ*, 43 F.3d 312, 316–17 (7th Cir. 1994) (holding that agency's response to subpoena under *Touhy* "is subject to judicial review" and "has to be an APA claim directed at the agency, the United States, or the employee thereof" and

"must be in federal court pursuant to 5 U.S.C. § 702"); *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, No. 3:19-md-2885, 2021 WL 219917, at *4 (N.D. Fla. Jan. 4, 2021) (explaining that a challenge to an "agency's decision . . . on a motion to quash or motion to compel" is governed by the APA's "arbitrary and capricious" standard); *Rhoads v. U.S. Dep't of Veterans Affs.*, 242 F. Supp. 3d 985, 990 (E.D. Cal. 2017) ("The remedy for challenging an agency's decision not to authorize testimony is a separate action in federal court pursuant to the APA.").[1]

Under the APA, a reviewing court must set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A). When a court applies the APA's "arbitrary and capricious" standard of review, it "must 'ascertain whether the agency examined the relevant data and articulated a rational connection between the facts found and the decision made.'" *Kobach v. U.S. Election Assistance Comm'n*, 772 F.3d 1183, 1197 (10th Cir. 2014) (quoting *Aviva Life & Annuity Co. v. FDIC*, 654 F.3d 1129, 1131 (10th Cir. 2011)); *see also Brown v. U.S. Dep't of Veterans Affs.*, No. 2:17-cv-1181-TMP, 2017 WL 3620253, at *5 (N.D. Ala. Aug. 23, 2017) ("At a minimum, the agency must have considered relevant data and articulated an explanation establishing a rational connection between the facts found and the choice made." (citation and internal quotation marks omitted)). As our Circuit has explained,

> An agency action is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or if the agency action is so implausible

[1] As one Colorado federal court has observed, "there is limited case law in the Tenth Circuit regarding application of the *Touhy* doctrine[.]" *Quezada v. Mink*, No. 10-cv-00879-REB-KLM, 2010 WL 4537086, at *3 (D. Colo. Nov. 3, 2010). The court's research reveals no Tenth Circuit cases that have considered the VA's *Touhy* regulations in a challenge to the VA's refusal to respond to discovery requests. Thus, here, the court relies on decisions from outside our Circuit as persuasive authority when addressing the question whether the VA's refusal to produce documents and information to plaintiff Schroeder and intervenor plaintiff Medtronic based on the agency's *Touhy* regulations violated the APA.

> that it could not be ascribed to a difference in view or the product of agency expertise."

Diné Citizens Against Ruining Our Env't v. Haaland, 59 F.4th 1016, 1029 (10th Cir. 2023) (quoting *Wyoming v. U.S. Dep't of Agric.*, 661 F.3d 1209, 1227 (10th Cir. 2011)); *see also Rhoads*, 242 F. Supp. 3d at 990.

This arbitrary and capricious standard of review "is very deferential to the agency's determination, and a presumption of validity attaches to the agency action such that the burden of proof rests with the party challenging it." *Kobach*, 772 F.3d at 1197 (citations and internal quotation marks omitted); *see also Diné Citizens*, 59 F.4th at 1029 (explaining that our Circuit "accord[s] agency action a presumption of validity" and the party challenging an agency decision "'bears the burden of persuasion' to show that the agency action is arbitrary and capricious" (citation and internal quotation marks omitted)).

III. Analysis

The court begins its analysis with plaintiff Schroeder's APA claim and his request that the court compel the VA to produce certain documents and information responsive to his discovery requests. After that analysis concludes, the court turns to intervenor-plaintiff Medtronic's APA claim and its request for a court order compelling the VA to produce certain documents and information in response to its discovery requests.

A. Plaintiff Schroeder's APA Claim

Plaintiff Schroeder asserts that the VA's refusal to produce certain documents and information in response to his discovery requests was arbitrary and capricious, and thus, unlawful under the APA. As a consequence, and using plaintiff Schroeder's words to describe the requested order, he asks the court to issue an order:

1. Compelling the VA to produce the requested numerical data regarding the annual number of patients treated with interventional procedures by interventional radiologists at the Dole VA cath lab for the years 2011 through 2018, along with submission of reasonable charges for that production of data;

2. Compelling the VA to produce the requested statistically acceptable sample (as to be determined by Plaintiff's expert) of fully redacted medical records relating to peripheral arterial disease procedures at the Dole VA cath lab for the years 2011 through 2018, along with submission of reasonable charges for that production of records;

3. Compelling the VA to produce copies of all documents relating to the VA's investigation into the conduct at the Dole VA's cath lab involving WRG and Medtronic, Inc., and specifically: all emails and communications among the task force formed by Dole VA Medical Center Director Ament regarding the investigation, along with submission of reasonable charges for that production of documents; and,

4. Compelling the VA to produce copies of all documents relating to any audits or studies comparing the costs or clinical outcomes of performing procedures at the Dole VA's cath lab to other VA facilities performing the same procedures, as well as remanding the matter back to the VA in order to reconsider and resubmit reasonable charges for that production of documents.

Doc. 32 at 28. The court addresses each of the four requests, in turn, below.[2]

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[2] Plaintiff Schroeder also asks the court to consider documents outside the administrative record when deciding whether the VA violated the APA by denying certain requests for documents and information made by plaintiff Schroeder. When a court evaluates whether an agency has complied with the APA, its review "'is generally based on the full administrative record that was before all decision makers.'" *Rocky Mountain Peace & Just. Ctr. v. U.S. Fish & Wildlife Serv.*, 40 F.4th 1133, 1160 (10th Cir. 2022) (quoting *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993)). "'The complete administrative record consists of all documents and materials directly or indirectly considered by the agency.'" *Id.* (quoting *Bar MK Ranches*, 994 F.2d at 739). Only in "'extremely limited' circumstances, a court may supplement the administrative record or consider extra-record evidence." *Id.* (quoting *Am. Mining Cong. v. Thomas*, 772 F.2d 617, 626 (10th Cir. 1985)). Those circumstances "include when (1) 'the record is deficient because the agency ignored relevant factors it should have considered,' (2) 'the agency considered factors that were left out of the formal record,' and (3) 'evidence coming into existence after the agency acted demonstrates that the actions were right or wrong.'" *Id.* (quoting *Am. Mining Cong.*, 772 F.2d at 626).

Plaintiff here argues that the court should invoke one of these exceptions. Specifically, he urges the court to consider certain affidavits and deposition testimony in this APA action because "the VA ignored several relevant factors when considering" plaintiff Schroeder's requests. Doc. 32 at 15. The court concludes that it doesn't need to consider materials outside the administrative record to decide that the VA's refusal to provide documents and information in response to plaintiff Schroeder's *Touhy* requests was arbitrary and capricious. Thus, it declines plaintiff Schroeder's invitation to consider these additional materials. Also, it denies plaintiff Schroeder's Motion for Leave to Supplement his Opening Brief (Doc. 45) with additional argument based on recently acquired deposition testimony.

1. Numerical Data

First, plaintiff Schroeder asserts that the VA's refusal to produce certain numerical data was arbitrary and capricious. As already explained, plaintiff Schroeder submitted a *Touhy* request to the VA seeking data "reflecting the annual number of interventional procedures performed at the Dole VA cath lab by interventional radiologists for the years 2011 through 2018." Doc. 14-2 at 167 (AR 534). The VA responded to plaintiff Schroeder that it would not produce the requested data and that it objected to the request because the documents are medical records "that are protected by the Privacy Act, HIPAA, FOIA, and/or related privacy statutes." *Id.* Also, the VA stated that it would cost an estimated $21,387.52 for the VA to produce the data and records sought by this request and the related request for a statistically acceptable sample of medical records (discussed in the subsection below). *Id.* at 169 (AR 536).

The VA asserts that it properly considered its *Touhy* regulations when it decided to deny this request. Specifically, the VA contends that 38 C.F.R. § 14.804(f)'s "confidentiality" factor precludes the VA from producing this information because it "would violate a confidentiality statute's prohibition against disclosure[.]" 38 C.F.R. § 14.804(f); *see also* Doc. 38 at 14.

The problem with the VA's argument is that it ignores that the request seeks only *numerical* data reflecting the number of patients who received certain procedures at the Dole VA. As plaintiff Schroeder argues, this "request seeks numbers and numbers only." Doc. 32 at 24. It doesn't ask for any identifying information for these patients or any underlying medical records. Thus, the VA's reliance on § 14.804(f)'s confidentiality factor fails to "set forth a 'rational connection between the facts found and the choice made.'" *OhioHealth Corp. v. U.S. Dep't of Veteran Affs.*, No. 2:14-cv-292, 2014 WL 4660092, at *6 (S.D. Ohio Sept. 17, 2014) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43

(1983)); *see also id.* (finding VA's denial of *Touhy* requests was arbitrary and capricious where the VA "offered no connections, just conclusions" for the basis of its denial); *Kobach v. U.S. Election Assistance Comm'n*, 772 F.3d 1183, 1197 (10th Cir. 2014) (explaining that when a court applies the APA's "arbitrary and capricious" standard of review, it "must 'ascertain whether the agency examined the relevant data and articulated a rational connection between the facts found and the decision made'" (quoting *Aviva Life & Annuity Co. v. FDIC*, 654 F.3d 1129, 1131 (10th Cir. 2011))).

Also, the VA failed to consider plaintiff Schroeder's offer to pay the costs associated with producing the requested numerical data. Doc. 14-2 at 140 (AR 507) (asserting in January 4, 2022 letter that there "should not be any expenditures of money as Relator is prepared to cover any incurred costs for labor, copying, *etc.*, and is willing to cover such costs up front"). While two of the VA's *Touhy* factors—subsection (a)'s "need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel" factor and subsection (d)'s "unduly burdensome" factor—provide a reason to deny the request based on the costs associated with gathering and producing the data, *see* 38 C.F.R. § 14.804(a), (d), plaintiff Schroeder's offer to pay the costs incurred by the VA for producing the requested information nullifies this concern. The administrative record doesn't show that the VA considered that offer in light of the relevant *Touhy* factors. Thus, the VA's decision to deny the request for this numerical data was arbitrary and capricious. *See Rhoads*, 242 F. Supp. 3d at 995, 997 (holding that VA's refusal to allow depositions of employees was "arbitrary, capricious, and an abuse of discretion" when "the VA's response to Plaintiffs' request under *Touhy* fail[ed] to address Plaintiffs' offer to accommodate VA employees' work schedules and to consider the burden in light of other important factors").

Finally, and as plaintiff Schroeder argues, the VA already has demonstrated that it has the ability to gather and produce this type of data because it did so in its own internal investigation. *See* Doc. 14-1 at 345–64 (AR 341–60) (producing emails, data, and other information—including patient lists—that the VA had gathered in March and April 2018). And it did so in a relatively short order—less than three months' time. *Id.* Thus, to the extent the VA relied on subsection (a)'s "need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel" factor and subsection (d)'s "unduly burdensome" factor to deny this request, *see* 38 C.F.R. § 14.804(a), (d), its reliance wasn't reasonable in light of the VA's ability to gather and produce this same type of information in its own investigation.

For all these reasons, the administrative record demonstrates that the VA's decision to deny plaintiff Schroeder's request for numerical data showing the annual number of patients with interventional procedures performed at the Dole VA catheterization lab between 2011 and 2018 was arbitrary and capricious.

2. Statistical Sample

Second, plaintiff Schroeder asserts that the VA's refusal to produce a statistical sample of medical records was arbitrary and capricious. As discussed, plaintiff Schroeder submitted a *Touhy* request to the VA seeking a "statistically acceptable sample of patients' medical records regarding interventional procedures performed in the Dole VA cath lab by interventional radiologists for the years 2011 through 2018." Doc. 14-2 at 167 (AR 534). The VA's September 20, 2022 letter advised plaintiff Schroeder that the VA wouldn't produce these documents for the same confidentiality reasons it had declined to produce the data discussed in subpart 1., above. *Id.* And, as discussed, the VA asserted that it would cost an estimated $21,387.52 for the VA to

produce the data and records sought by both this request and the numerical data request discussed in the above paragraph. *Id.* at 169 (AR 536).

Plaintiff Schroeder asserts that the VA's reliance on § 14.804(f)'s confidentiality factor was arbitrary and capricious because the VA failed to consider his agreement to redact fully any personal identifying information from the medical records. *See* Doc. 14-2 at 156 (AR 523) (suggesting to the VA that "any information that might include a patient's name or identity can be redacted" (citing 38 U.S.C. § 5705(b)(2))). Also, plaintiff Schroeder explained to the VA that "a protective order is in place" in the underlying qui tam lawsuit "that will permit documents and testimony to be kept 'confidential' under that order's terms." *Id.* The VA's denial of plaintiff Schroeder's request failed to consider these measures available to protect confidentiality. And thus, the VA's denial of the request based on § 14.804(f)'s confidentiality factor fails to "set forth a 'rational connection between the facts found and the choice made.'" *OhioHealth Corp.*, 2014 WL 4660092, at *6 (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43); *see also Kobach*, 772 F.3d at 1197 (instructing courts applying the APA's "arbitrary and capricious" standard to "ascertain whether the agency examined the relevant data and articulated a rational connection between the facts found and the decision made" (citation and internal quotation marks omitted)).

The VA also discussed—albeit generally—several other *Touhy* factors. Specifically, the VA cited a litany of other factors that purportedly supports its refusal to produce the requested medical records. *See* Doc. 38 at 13–14; *see also* Doc. 14-2 at 162–65 (AR 529–32) (discussing factors found in § 14.804(a), (d), (*l*)). But an agency's "denial letters" consisting "largely of generalized assertions that [do] not appear to take into account the arguments and affidavits submitted in support of [the] *Touhy* requests" don't qualify as a proper denial under the APA. *OhioHealth Corp.*, 2014 WL 4660092, at *5 (holding that "use of this [generalized] language

does little to convince the Court that the VA examined the specific evidence before it and the merits of Plaintiffs' particular *Touhy* requests"). Here, the VA issued a generalized denial based on the § 14.804(a), (d), and (*l*) factors. But the VA never tried to explain why the facts relevant here support denying plaintiff Schroeder's requests.

For the factor in subsection (a)—the "need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel"—the VA's denials never addressed plaintiff Schroeder's offer to pay the costs associated with gathering and producing the documents. Thus, it wasn't reasonable to deny the request based on costs associated with producing the information. Also, the VA's claim that plaintiff Schroeder's request is for "private purposes" ignores that he brings a qui tam action—on behalf of the United States—to recover allegedly fraudulent payments made by the United States, induced by the qui tam defendants' alleged illegal kickback scheme. It also disregards that this alleged scheme caused the VA to provide unnecessary medical treatment to its veteran patients. *See Rhoads*, 242 F. Supp. 3d at 993–95 (holding that VA's reliance on § 14.804(a) factor was arbitrary and capricious where the underlying lawsuit for which plaintiff sought discovery "directly implicate[d] the health and wellbeing of VA employees and patients as a result of an incident that occurred at the Oakhurst Clinic"); *cf. In re 3M Combat Arms Earplug Prods. Liab. Litig.*, Nos. 3:19-md-2885, 3:20-mc-49, 2020 WL 5994266, at *7 (N.D. Fla. Oct. 9, 2020) ("[A]ny 'need to avoid spending the time and money of the United States for private purposes,' § 14.804(a), does not grant the VA an absolute evidentiary privilege from third-party discovery requests not enjoyed by other disinterested witness[es]."). Thus, the VA's general reliance on the § 14.804(a) factor fails "to articulate a rational connection between the facts and its decision

to not . . . produce records." *See In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2020 WL 5994266, at *5.

For the factor in subsection (d)—the "unduly burdensome" factor—the VA's refusal to produce the requested medical records never considered plaintiff Schroeder's offer to pay the VA's costs for making the production. Thus, the VA can't rely on costs associated with the *Touhy* request as a proper reason to deny the request as unduly burdensome. And while the VA's denial letters asserted that the time required for VA staff to respond to the requests imposes an undue burden on the agency, the VA merely provided a time estimate for the production. But the VA didn't provide any further explanation for why staff couldn't devote that amount of time to the production. *See* Doc. 14-2 at 169 (AR 536) (estimating that it would take 352 hours for one "System Analysist" to gather the information responsive to both the numerical data and statistical sample requests but providing no explanation whether the VA has but one "System Analysist" who could perform the work). This response didn't "explain how [plaintiff Schroeder's] particular *Touhy* requests would affect the . . . official duties" of VA employees and staff sufficient to deny the requests based on § 14.804(d)'s "unduly burdensome" factor. *See OhioHealth Corp.*, 2014 WL 4660092, at *6 (finding that "VA did not explain why Plaintiffs' request was unduly burdensome" when "the VA made no indication that the physician's patient load, schedule, or other official duties would be hampered by complying with Plaintiffs' request"); *see also In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2020 WL 5994266, at *6 ("Workload, however, is not a rational basis to excuse" discovery because, if it was, "the review process for federal courts would be illusory, and agency action would go unchecked" simply by "claim[ing] an employee is 'too busy' to participate in discovery and the requesting party would have little, if any, room to refute this contention for the Court to undertake meaningful review").

Also, as already discussed, the administrative record shows that the VA has the ability to gather and produce this type of data because it did so earlier as part of its own internal investigation, completing the work within three months' time. *See* Doc. 14-1 at 345–64 (AR 341–60). Thus, the VA's denial of plaintiff Schroeder's request for a statistical sample of medical records failed to provide a "'rational connection between the facts found and the choice made'" to deny the request based on § 14.804(d)'s "unduly burdensome" factor. *OhioHealth Corp.*, 2014 WL 4660092, at *7 (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43).

And for the factor in subsection (*l*)—the "need to minimize VA's possible involvement in issues unrelated to its mission"—the VA's denials generally asserted that it "should not be required to allocate resources to reviewing its extensive files to respond to [plaintiff Schroeder's] broad requests." Doc. 14-2 at 163 (AR 530). But the VA never articulated a rational connection for denying the request based on this subsection (*l*) factor.

As plaintiff Schroeder asserts, the VA's stated mission is:

> To fulfill President Lincoln's promise—"To care for him who shall have borne the battle, and for his widow, and his orphan"—by serving and honoring the men and women who are America's Veterans.

U.S. Dep't of Veterans Affairs, https://www.va.gov/fund/docs/annualreports/mda10.pdf (last visited Apr. 26, 2023).[3] Plaintiff Schroeder asserts that his qui tam lawsuit is directly related to the VA's mission of providing medical care for veterans. Indeed, the underlying qui tam lawsuit alleges that the qui tam defendants engaged in an illegal kickback scheme resulting in the VA providing unnecessary medical care and promoting off-label use of devices on Dole

[3] The court may take judicial notice of some kinds of factual information contained on a website. *See O'Toole v. Northrop Grumman Corp.*, 499 F.3d 1218, 1225 (10th Cir. 2007) ("It is not uncommon for courts to take judicial notice of factual information found on the world wide web."); *see also Buhendwa v. Reg'l Transp. Dist.*, 82 F. Supp. 3d 1259, 1262 n.1 (D. Colo. 2015) (explaining that a court may take judicial notice of information on a state agency's website (citing *Coleman v. Dretke*, 409 F.3d 665, 667 (5th Cir. 2005))).

VA's veteran patients. While the VA isn't a party to the underlying lawsuit, the qui tam allegations, if proven true, bear some relation to the VA's mission. *See In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2020 WL 5994266, at *1 (explaining that the lawsuit involved plaintiffs who "are servicemembers, veterans, and civilians seeking damages in this action for hearing loss, tinnitus, and related injuries caused by their use of" earplugs and noting that while the "Government is not a party to this litigation, . . . its relationship to this matter is undeniable"). But the VA's denial letters never explained why the VA had concluded that the qui tam lawsuit's allegations are unrelated to the VA's mission—except to say that it didn't want to devote resources to plaintiff Schroeder's request. Thus, the VA failed "to articulate a rational connection between the facts and its decision to not . . . produce records" based on the § 14.804(*l*) factor. *See In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2020 WL 5994266, at *5.

Also, plaintiff Schroeder correctly asserts that the VA's denial failed to consider other factors relevant to the decision whether to produce the requested statistical sample of medical records. For example, the VA never addressed § 14.804(b)'s factor. Subsection (b) directs the VA to consider how "production of records would assist VA in performing its statutory duties[.]" 38 C.F.R. § 14.804(b). Nor did it address § 14.804(c)'s factor. Subsection (c) instructs the VA to consider whether "disclosure of the records . . . is necessary to prevent the perpetration of fraud or other injustice in the matter in question." 38 C.F.R. § 14.804(c). Although "the VA does not have to consider *all* of the factors listed in 38 C.F.R. § 14.804," courts have found relevant an agency's "failure to address one of the most important aspects of" a *Touhy* request. *OhioHealth Corp.*, 2014 WL 4660092, at *6 (citation omitted); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43 (explaining that an agency's decision might qualify as "arbitrary and capricious"

if the agency "entirely fail[s] to consider an important aspect of the problem"); *see also Portaleos v. Shannon*, Nos. 5:12-CV-1359 (LEK/TWD), 5:12-CV-1652 (LEK/TWD), 2013 WL 4483075, at *6 (N.D.N.Y. Aug. 19, 2013) (finding "the VA's apparent failure to consider factor (e)" was "inexplicable" and "render[ed] the VA's decision not to authorize [a doctor's] testimony arbitrary and capricious"). Here, the VA never considered the factors in subsection (b) and (c) even though the requested documents are highly relevant to proving (or disproving) plaintiff Schroeder's fraud claims in the qui tam action. Also, relevant to the subsection (b) and (c) factors, the VA's own investigation of the allegations asserted against the catheterization lab's practices noted that "[e]vidence based medicine not followed in majority of the cases[;]" found that it seemed "like over utilization of [drug coated balloons] and atherectomy devices[;]" and questioned whether the "cocktail of devices used in quite a few cases" was "really [warranted] even though the end results are not that different and add to complications." Doc. 14-1 at 335 (AR 331). These facts appear highly germane to subsection (b)'s factor, *i.e.*, "assist[ing] VA in performing its statutory duties[,]" and subsection (c)'s factor of "prevent[ing] the perpetration of fraud or other injustice in the matter in question." 38 C.F.R. § 14.804(b), (c). Yet, the VA never considered these factors in its decision whether to produce the requested medical records.

And there's another significant omission from the VA's decision not to produce the statistical sample of medical records. The VA's correspondence with plaintiff Schroeder never considered that he has no other means to discover the information that he seeks. As plaintiff Schroeder aptly explains, he needs these medical records to prove his False Claims Act claims in the underlying qui tam lawsuit—*i.e.*, these medical records could support his allegations that Medtronic paid illegal remuneration to employees at the Dole VA, thus causing the VA to

purchase a grossly excessive number of medical devices, provide unnecessary medical treatment, and promote off-label use of devices on Dole VA's veteran patients. And plaintiff Schroeder has no other means to discover these medical records—as well as the numerical data sought in the request discussed above—unless the VA produces the information to him. Thus, the VA "failed to consider an important aspect of the problem"—specifically, plaintiff Schroeder's inability to procure the information from elsewhere—when it denied his *Touhy* request. *Rhoads*, 242 F. Supp. 3d at 990 (citation and internal quotation marks omitted); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43 (explaining that an agency violates the "arbitrary and capricious" standard if it "entirely fail[s] to consider an important aspect of the problem").

For all these reasons, the court concludes that the administrative record fails to demonstrate "a rational connection between the facts found and the decision made." *Kobach*, 772 F.3d at 1197 (citation and internal quotation marks omitted); *see also Brown*, 2017 WL 3620253, at *5 ("At a minimum, the agency must have considered relevant data and articulated an explanation establishing a rational connection between the facts found and the choice made." (citation and internal quotation marks omitted)). Thus, the administrative record supports plaintiff Schroeder's claim that the VA's refusal to produce a statistical sample of medical records was arbitrary and capricious.

3. Documents Relating to Investigation

Third, plaintiff Schroeder asserts that the VA's refusal to produce documents about its investigation of the Dole VA catheterization lab was arbitrary and capricious. As already explained, plaintiff Schroeder submitted a *Touhy* request seeking "[d]ocuments that address any complaints or investigation into conduct at the Dole VA's catheterization lab involving Medtronic, Inc. or Covidien, Inc., or their representatives[.]" Doc. 14-3 at 31 (AR 578). The

VA has produced some documents responsive to this request, but plaintiff Schroeder believes that additional documents exist and they are responsive to this document request, but the VA has refused to produce them. *See* Doc. 32 at 12 (citing AR 1–360). Specifically, plaintiff Schroeder seeks: (1) all emails and other communications among a task force formed by the Dole VA Medical Center Director Ament about any investigations or audits into the conduct at the Dole VA's cath lab involving WRG and Medtronic, Inc., and (2) all communications involving Dr. Feroz Maqbool who the Dole VA brought in from the Oklahoma VA to review and comment on the peripheral procedures performed at the Dole VA cath lab as part of its internal investigation. Doc. 32 at 25.

In an August 15, 2022 letter, the VA declined to produce additional records about its investigation of the Dole VA catheterization lab, citing three of § 14.804's factors—the ones found in subsections (a), (i), and (*l*). Doc. 14-3 at 32 (AR 579). For many of the same reasons already discussed, the VA's refusal to produce these additional documents about the VA's investigation of the Dole VA's catheterization lab doesn't "articulat[e] an explanation establishing a rational connection between the facts found and the choice made." *See Brown*, 2017 WL 3620253, at *5 (citation and internal quotation marks omitted). Instead, the VA's denial letter consists "largely of generalized assertions that [do] not appear to take into account the arguments and affidavits submitted in support of [the] *Touhy* requests" and doesn't "convince" the court that the "VA examined the specific evidence before it and the merits of" plaintiff Schroeder's "particular *Touhy* requests." *OhioHealth Corp.*, 2014 WL 4660092, at *5.

The VA's reliance on § 14.804(a)'s "need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel" factor and subsection (*l*)'s "need to minimize VA's possible involvement in issues unrelated to its mission"

factor fails to consider that plaintiff Schroeder's qui tam lawsuit—one that alleges that defendants perpetrated a fraud on the VA (and, in turn, on the United States government) and resulted in unnecessary medical treatment to VA patients—isn't purely a lawsuit involving "private purposes" and appears to have some relation to the VA's mission. Also, the VA never considered that plaintiff Schroeder offered to pay the costs incurred by the VA to produce the requested documents—something that weighs against the VA's reliance on subsection (a)'s factor to deny the *Touhy* requests.

Also, the VA never explained why subsection (i)'s "appearance of VA or the Federal government favoring one litigant over another" factor disfavors producing the documents and information. While producing the documents would grant the *Touhy* requests made by plaintiff Schroeder, the documents—in the end—might not lend support to his False Claims Act claims in the qui tam lawsuit. As plaintiff Schroeder asserts, the documents and information "could very well provide support to the [qui tam] Defendants' defenses." Doc. 32 at 26. Thus, it's unclear from the administrative record why the VA believed that producing the investigation documents would favor one litigant over another.

And, for the same reasons already discussed, the VA's refusal to produce certain documents about the VA's investigation failed to consider other relevant factors supporting plaintiff Schroeder's *Touhy* requests. Again, the VA never considered the subsection (b) and (c) factors. They direct the VA to consider how the "production of records would assist VA in performing its statutory duties[,]" 38 C.F.R. § 14.804(b), and whether "disclosure of the records . . . is necessary to prevent the perpetration of fraud or other injustice in the matter in question[,]" 38 C.F.R. § 14.804(c). Based on plaintiff Schroeder's qui tam allegations and the information already revealed by the VA's own investigation of the Dole VA's catheterization lab practices

(*see* Doc. 14-1 at 332–64 (AR 328–60)), these factors appear relevant to the decision whether to produce the requested documents. By failing to address the subsection (b) and (c) factors, it appears that the VA failed "to address one of the most important aspects of" a *Touhy* request. *OhioHealth Corp.*, 2014 WL 4660092, at *6 (citation omitted); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43 (explaining that an agency's decision might qualify as "arbitrary and capricious" if the agency "entirely fail[s] to consider an important aspect of the problem").

Also, it doesn't appear that the VA ever considered that plaintiff Schroeder has no other means to discover the information he seeks. Indeed, only the VA possesses the documents and information about its investigation into the practices of the Dole VA's catheterization lab. The results of that investigation are relevant to plaintiff Schroeder's False Claims Act allegations in the qui tam lawsuit. And he has no other means to discover the investigative material unless the VA produces the information to him. Thus, when denying the *Touhy* request, the VA failed to consider plaintiff Schroeder's inability to procure the information from elsewhere—something that is "an important aspect of the problem." *Rhoads*, 242 F. Supp. 3d at 990 (citation and internal quotation marks omitted); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43 (explaining that an agency violates the "arbitrary and capricious" standard if it "entirely fail[s] to consider an important aspect of the problem").

For all these reasons, the court concludes that that VA violated the APA when it denied plaintiff Schroeder's *Touhy* requests for certain documents relating to the VA's investigation of the practices of the Dole VA catheterization lab.

4. Documents Reflecting Comparison Audits or Studies

Fourth, plaintiff Schroeder asserts that the VA's refusal to produce documents reflecting "any audits or studies comparing the costs or clinical outcomes of performing procedures at the

Dole VA's catheterization lab compared to other facilities performing the same procedures" was arbitrary and capricious. Doc. 14-2 at 165–66 (AR 532–33). In the September 20, 2022 letter, the VA agreed to produce some documents responsive to this request that did "not require an extensive/time consuming search of its records, and [was] not protected by privacy laws[.]" *Id.* at 166 (AR 533). But the VA refused to produce any "other documents that require an extensive/time consuming search . . . until the [VA] receives payment from [plaintiff Schroeder]" for the costs of producing the documents. *Id.* The VA estimated the costs of the production as $17,443.20. *Id.* at 169 (AR 536).

Plaintiff Schroeder asserts that the VA's estimated costs for the production "are excessive for what is being requested." Doc. 9 at 7 (First Am. Compl. ¶ 25.c.). Plaintiff Schroeder argues that his request isn't onerous—and thus doesn't require the VA to spend the estimated sum. Plaintiff Schroeder argues that this much is evident based on the VA's ability to gather patient data for two years' worth of procedures at the Dole VA in relatively short order to use in its own internal investigation. *See* Doc. 14-1 at 345–64 (AR 341–60). The VA's correspondence asserted that producing this information will require 160 hours of time by a "QM" and 160 hours of time by a "System Analysist." Doc. 14-2 at 169 (AR 536). But the correspondence doesn't articulate a rational connection between the time estimates and the documents and information that plaintiff Schroeder is seeking for comparison audits or studies. This is particularly true given that that the VA's records show that it was able to gather other data in a short window of time as part of its internal investigation. Thus, the court concludes that the VA's denial of this particular request was arbitrary and capricious because the VA "offered no connections, just conclusions" for the basis of its denial. *OhioHealth Corp.*, 2014 WL 4660092, at *6; *see also Kobach*, 772 F.3d at 1197 (explaining that the APA requires an agency to "'examine[ ] the

relevant data and articulate[ ] a rational connection between the facts found and the decision made'" (quoting *Aviva Life & Annuity Co.*, 654 F.3d at 1131)).

In sum, the court concludes that the administrative record doesn't reflect a sufficient explanation for the VA's decision denying the above-described four *Touhy* requests. Because the VA didn't provide any "rational connection between the facts found and the choice made[,]" the VA's decision to deny the requests was arbitrary and capricious, and thus, violated the APA. *Motor Vehicle*, 463 U.S. at 43.

5. Remedy for APA Violations

Having concluded that the VA violated the APA by denying plaintiff Schroeder's *Touhy* requests, the court now must determine the proper remedy for these APA violations. Plaintiff Schroeder seeks an order compelling the VA to produce the requested documents and information. For support, plaintiff Schroeder asserts that the VA has stated that it won't disclose medical records without a court order. Doc. 32 at 24 n.3. The court doesn't read the VA's statements quite that rigidly. Instead, the VA simply has noted that it can't disclose medical records "without the consent of the person whose information is sought, or an appropriate court order to comply with statutory requirements governing confidentiality" such as HIPPA and other federal statutes. Doc. 38 at 14–15 (citing Doc. 14-2 at 163, 165–67 (AR 530, 532–34)). But it's not clear whether the response from the VA considered plaintiff Schroeder's offer to redact personal identifying information and whether those redactions would cure the need for a court order before production.

Also, the lone case that plaintiff Schroeder cites to support his request for an order compelling production is an Alabama federal district court case. Doc. 32 at 24 n.3. In *Brown v. United States Department of Veterans Affairs*, the court found that the VA's decision refusing to

permit a doctor's deposition was "arbitrary, capricious, and an abuse of discretion under the Administrative Procedures Act[.]" 2017 WL 3620253, at *9. And it ordered the Secretary of the VA to allow the doctor's deposition and produce documents sought by a subpoena duces tecum. *Id.* *Brown* never discussed whether the court should remand the matter to the VA for further consideration. But that procedure, the VA argues, is the proper remedy for an APA violation. *See* Doc. 38 at 12–13. This time, the VA is right.

Indeed, most courts follow the Supreme Court's instruction that "'when the agency record is inadequate, "the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation."'" *Wildearth Guardians v. U.S. Forest Serv.*, 713 F. Supp. 2d 1243, 1265 (D. Colo. Apr. 1, 2010) (quoting *Sierra Club-Black Hills Grp. v. U.S. Forest Serv.*, 259 F.3d 1281, 1289 (10th Cir. 2001) (quoting *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985))); *see also Hazlehurst v. Ctrs. for Disease Control*, No. 1:17-cv-02095-STA-egb, 2017 WL 3037808, at *1 n.1 (W.D. Tenn. July 18, 2017) ("If the [c]ourt were to conclude that the denial was arbitrary and capricious, [p]laintiff is not entitled to injunctive and declaratory relief; instead, the proper remedy would be to remand the matter to the CDC for further consideration." (citation omitted)). And—outside of *Brown*—the federal courts who have found the VA violated the APA by denying *Touhy* requests have remanded the issues to the VA to reconsider them in light of the court's conclusions. *See, e.g.*, *Rhoads*, 242 F. Supp. 3d at 997 (finding that "VA's determination not to allow . . . nurses to testify was arbitrary and capricious" but that "the proper remedy is not a *de novo* review by this [c]ourt of whether the VA ought to authorize its employees to be deposed" and "[i]nstead," remanding "the issue back to the VA for additional consideration and explanation consistent with [the] opinion"); *OhioHealth Corp.*, 2014 WL 4660092, at *7 (remanding *Touhy* denial because "[i]t is not the [c]ourt's place

. . . to issue a new decision based on a *de novo* inquiry of this matter. Instead, the proper remedy is to remand this issue back to the VA for further investigation and explanation." (citing *Fla. Power & Light*, 470 U.S. at 744)); *Portaleos*, 2013 WL 4483075, at *6 (drawing "no conclusion as to whether the VA is obligated to produce [doctor] for testimony," and instead "remand[ing] the matter for reconsideration of [p]laintiff's request within sixty days" (citations and internal quotation marks omitted)).

Consistent with this persuasive authority, the court remands the matter to the VA for reconsideration of plaintiff Schroeder's *Touhy* requests in light of the conclusions reached in this Order. The court is mindful of the time constraints involving expert discovery in the underlying qui tam lawsuit. Thus, the court directs the VA to undertake and conclude further consideration of the matter within 30 days of this Order. And it asks the VA to heed the time constraints of the underlying qui tam lawsuit when it is reconsidering the matter.

B. Medtronic's APA Claim

Medtronic asserts that the VA's refusal to produce certain documents and information in response to its discovery requests was arbitrary and capricious and, thus, unlawful under the APA. As a consequence, Medtronic asks the court to issue an order compelling the VA to produce documents responsive to the following requests:

- Request No. 2: Any documents, correspondence, or analysis of the positive benefits of the Dole VA's treatment of peripheral vascular disease to the health and outcomes of veterans from 2011 to current.

- Request No. 3: For 2011 to 2021, communications between Dole VA employees, specifically employees of the catheterization lab or those involved in purchasing or procurement of peripheral vascular devices, and company or sales representatives that sell peripheral vascular devices, including but not limited to Relator Thomas Schroeder, Todd Brown, Dan Clinkscales, Dan Tebbe, Chris Mattingly, Mitch Miller, Michael Fara, and Larry Valdivia.

- Request No. 5: For the 11 VA facilities, Relator put at issue (Loma Linda, San Antonio, Milwaukee, Miami, North Las Vegas, St. Louis, Oklahoma City, Dallas, Baltimore, Des Moines, Jesse Brown (Chicago)), documents or data in the following subcategories for the period of 2011 to 2020:

    a. Documents or data sufficient to show the identity of any physician performing the peripheral vascular procedures;
    b. Documents or data sufficient to show the number of peripheral vascular procedures performed on a monthly basis;
    c. Documents or data sufficient to show the date, price, and volume of all peripheral vascular devices purchased from any manufacturer for use at that VA;
    d. For each patient who underwent a peripheral vascular procedure, documents sufficient to show the patient's underlying medical condition at the time the peripheral vascular procedure was performed;
    e. For each patient who underwent a peripheral vascular procedure, documents showing the physician's medical basis for the treatment decisions related to the peripheral vascular procedure.
    f. Any documents related to off-label use of peripheral vascular devices during the relevant time period.

- Request No. 6: To the extent information is provided to Relator in connection with his January 4, 2022 Requests (or as modified), Defendant also asks for the following materials from 2011 to current be provided to ensure a full and fair record is developed:

    a. Documentation of the request for proposal, evaluation, and decision to make bulk purchases of peripheral vascular devices for use at the Dole VA from 2011 to current, including any basis or rationale for volume purchased and type of device selected.
    b. Documents sufficient to show the purchase or inventory of non-Medtronic devices for use in the Dole VA catheterization lab from 2011 to current.
    c. Documents that show any input of or requests by physicians for certain medical devices to be used in the Dole VA catheterization laboratory from 2011 to current.

- Request No. 7: To the extent records relating to any patient procedures are provided to Relator, we request all documents related to:

    a. The patient's medical condition at the time of the peripheral vascular procedure; and
    b. The medical basis for treatment decisions for those patients made by physicians performing peripheral vascular procedure.

Doc. 37 at 10–12 (citing Doc. 25-1 at 3–5 (AR 694–96)).

As already discussed, the VA responded to Medtronic's *Touhy* requests by letter dated October 4, 2022. Doc. 25-1 at 12–26 (AR 703–17). The VA agreed to produce some documents responsive to one of Medtronic's document requests and permitted several depositions. *Id.* But the VA objected to the remaining document requests relying on factors found in 38 C.F.R. § 14.804(a), (d), (f), and (*l*). *Id.* at 13–14 (AR 704–05). Also, the VA provided a time and cost estimate for producing the requested documents and information, estimating about 6,117.25 hours and $266,474.89. *Id.* at 14 (AR 705).

Medtronic argues that the VA's decision denying its *Touhy* requests was arbitrary and capricious, and thus violated the APA, for several reasons.

First, Medtronic asserts that the VA unreasonably relied on subsection (a)'s "need to avoid spending the time and money of the United States for private purposes and to conserve the time of VA personnel" factor and subsection (d)'s "unduly burdensome" factor because the VA's decision failed to consider that Medtronic has offered to pay the reasonable costs associated with producing the documents. Also, Medtronic argues, it wasn't reasonable for the VA to rely on the subsection (f)'s "confidentiality" factor because the VA didn't take into account Medtronic's agreement to redact all personal identifying information from the documents.

The VA's general reliance on these three § 14.804 factors—as discussed in its October 4, 2022 letter, Doc. 25-1 at 12–26 (AR 703–17)—fails "to articulate a rational connection between the facts and its decision to not . . . produce records." *See In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2020 WL 5994266, at *5. As a Florida federal district court recently observed, "any 'need to avoid spending the time and money of the United States for private purposes,' § 14.804(a), does not grant the VA an absolute evidentiary privilege from third-party discovery requests not enjoyed by other disinterested witness[es]." *In re 3M Combat Arms*

Earplug Prods. Liab. Litig., 2020 WL 5994266, at *7. Also, the VA's response never explained how these "particular *Touhy* requests would affect the . . . official duties" of VA employees and staff sufficient to deny the requests based on § 14.804(d)'s "unduly burdensome" factor. *See OhioHealth Corp.*, 2014 WL 4660092, at *6 (finding that "VA did not explain why Plaintiffs' request was unduly burdensome" when "the VA made no indication that the physician's patient load, schedule, or other official duties would be hampered by complying with Plaintiffs' request"). And the VA's reliance on § 14.804(f)'s confidentiality factor fails to "set forth a 'rational connection between the facts found and the choice made'" when the VA's correspondence never considered that Medtronic had offered to redact all personal identifying information from the produced documents. *See OhioHealth Corp.*, 2014 WL 4660092, at *6 (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43); *see also id.* (finding VA's denial of *Touhy* requests was arbitrary and capricious where the VA "offered no connections, just conclusions" as the basis for its denial).[4]

Second, Medtronic asserts that the VA's decision to deny the *Touhy* requests failed to consider other relevant § 14.804 factors—specifically, the factor in subsection (e) directing the VA to consider whether "production of records . . . is appropriate or necessary under the rules of procedure governing the case or matter in which the demand or request arose[.]" 38 C.F.R. § 14.804(e). Although "the VA does not have to consider *all* of the factors listed in 38 C.F.R. §

[4] The parties' briefs don't discuss whether the VA reasonably relied on subsection (*l*)'s factor—*i.e.*, the "need to minimize VA's possible involvement in issues unrelated to its mission" factor. 38 C.F.R. § 14.804(*l*). For this factor, the VA's October 4, 2022 letter recited, simply: "The diversion of resources to meet your *Touhy* request would directly impact the mission and operation of the Department of Veterans Affairs. 38 [C.F.R. §] 14.804(*l*). The VA should not be required to allocate resources to reviewing its extensive files to respond to these broad requests." Doc. 25-1 at 14 (AR 705). This generalized response provides no "connections, just conclusions" to deny the request under subsection (*l*). *See OhioHealth Corp.*, 2014 WL 4660092, at *6 (finding VA's denial of *Touhy* requests was arbitrary and capricious where VA "offered no connections, just conclusions" as the basis for its denial).

14.804," courts have found relevant an "agency's failure to address one of the most important aspects of" a *Touhy* request. *OhioHealth Corp.*, 2014 WL 4660092, at *6 (citation omitted); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43 (explaining that an agency's decision might qualify as "arbitrary and capricious" if the agency "entirely fail[s] to consider an important aspect of the problem"); *see also Portaleos*, 2013 WL 4483075, at *6 (finding "the VA's apparent failure to consider factor (e)" was "inexplicable" and "render[ed] the VA's decision not to authorize [a doctor's] testimony arbitrary and capricious").

Here, Medtronic argues, the VA never considered that these records are necessary for Medtronic to defend against plaintiff Schroeder's claims in the underlying qui tam action. As discussed, the qui tam court has permitted plaintiff Schroeder—over Medtronic's objection—to seek fact discovery on peripheral vascular device use at 11 other VA facilities. Doc. 19 at (Intervenor Compl. ¶ 9); *see also* Doc. 41 at 6 (explaining that Medtronic served the VA with "Request No. 5 . . . because of an Order from Magistrate Judge Gale allowing Relator to conduct discovery *from Medtronic* on its sales to these 11 not-at-all at issue VA facilities over Medtronic's objection" (emphasis added)). Medtronic asserts that its *Touhy* requests seek additional information from the VA about these 11 other VA hospitals because the requested information will provide proper context for Medtronic's data about patient-specific device usage and device usage rates at these 11 other VA facilities. The court agrees with Medtronic. The VA "failed to consider an important aspect of the problem"—specifically, Medtronic's need to procure the information to provide context and a complete picture of device usage at these 11 other VA hospitals—when it denied Medtronic's *Touhy* requests. *Rhoads*, 242 F. Supp. 3d at 990 (citation and internal quotation marks omitted); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43

(explaining that an agency violates the "arbitrary and capricious" standard if it "entirely fail[s] to consider an important aspect of the problem").

Finally, Medtronic asserts that the VA's denial failed to recognize that Medtronic has no other means to discover the information that its document requests seek. Indeed, only the VA possesses the specific information that Medtronic seeks to defend against plaintiff Schroeder's qui tam lawsuit. And thus, Medtronic has no other means to discover the documents and information unless the VA produces them to Medtronic. Thus, the VA "failed to consider an important aspect of the problem"—specifically, Medtronic's inability to procure the information from elsewhere—when it denied certain of its *Touhy* requests. *Rhoads*, 242 F. Supp. 3d at 990 (citation and internal quotation marks omitted); *see also Motor Vehicle Mfrs.*, 463 U.S. at 43 (explaining that an agency violates the "arbitrary and capricious" standard if it "entirely fail[s] to consider an important aspect of the problem").

For all these reasons, the court concludes that the administrative record fails to demonstrate "a rational connection between the facts found and the decision made" by the VA when it denied certain of Medtronic's *Touhy* requests. *Kobach*, 772 F.3d at 1197 (citation and internal quotation marks omitted); *see also Brown*, 2017 WL 3620253, at *5 ("At a minimum, the agency must have considered relevant data and articulated an explanation establishing a rational connection between the facts found and the choice made." (citation and internal quotation marks omitted)). Thus, the administrative record supports Medtronic's claim that the VA's refusal to respond to certain of its *Touhy* requests was arbitrary and capricious. And, as a consequence, the court remands the matter to the VA for reconsideration of Medtronic's *Touhy* requests in light of the conclusions reached in this Order. *See Wildearth Guardians*, 713 F. Supp. 2d at 1265 ("[W]hen the agency record is inadequate, the proper course, except in rare

circumstances, is to remand to the agency for additional investigation or explanation." (citation and internal quotation marks omitted)); *see also OhioHealth Corp.*, 2014 WL 4660092, at *7 ("It is not the Court's place . . . to issue a new decision based on a *de novo* inquiry of this matter. Instead, the proper remedy is to remand this issue back to the VA for further investigation and explanation." (citing *Fla. Power & Light*, 470 U.S. at 744)).

IV. Conclusion

For reasons explained, the court finds that the VA violated the APA when it denied the *Touhy* requests submitted by plaintiff Schroeder and plaintiff-intervenor Medtronic, Inc. The court thus remands both matters to the VA for further consideration of the *Touhy* requests.

IT IS THEREFORE ORDERED BY THE COURT THAT plaintiff Thomas Schroeder has established that the United States Department of Veteran's Affairs violated the Administrative Procedures Act, 5 U.S.C. § 706, by denying certain of his *Touhy* requests. The court remands the matter to the Department of Veteran's Affairs for further consideration and supplemental response within 30 days of the date of this Order.

IT IS FURTHER ORDERED THAT plaintiff Thomas Schroeder's Motion for Leave to File a Supplement to His Opening Brief (Doc. 45) is denied.

IT IS FURTHER ORDERED THAT plaintiff-intervenor Medtronic, Inc. has established that the United States Department of Veteran's Affairs violated the Administrative Procedures Act, 5 U.S.C. § 706, by denying certain of its *Touhy* requests. The court remands the matter to the Department of Veteran's Affairs for further consideration and supplemental response within 30 days of the date of this Order.

IT IS FURTHER ORDERED THAT the court directs the Clerk of the Court to enter a judgment consistent with this Order and close the case.

IT IS SO ORDERED.

Dated this 16th day of May, 2023, at Kansas City, Kansas.

s/ Daniel D. Crabtree
Daniel D. Crabtree
United States District Judge